XGEVA® (Denosumab) Granted Marketing Authorization in the European Union

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Additional Year of Market Exclusivity Granted Based on Significant Clinical Benefit XGEVA Provides Over Existing Therapies

THOUSAND OAKS, Calif., July 15, 2011 /PRNewswire via COMTEX/ --

Amgen (NASDAQ: AMGN) today announced that the European Commission (EC) has granted marketing authorization for XGEVA® (denosumab) for the prevention of skeletal-related events (SREs) (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. This approval of XGEVA applies to all 27 European Union (EU) member states. The EC also granted XGEVA an additional year of data and market exclusivity in the EU since the indication was considered new for denosumab and based on the significant clinical benefit of XGEVA in comparison with existing therapies.

Bone metastases, the spread of cancer to the bones, are a common and serious concern for patients with advanced cancer and present a burden to the healthcare system. Weakened bones due to metastases can lead to SREs. The primary goal of treatment for bone metastases is to prevent the occurrence of these debilitating and costly SREs.

"Skeletal-related events associated with bone metastases are truly devastating and painful for patients living with cancer, and today's approval of XGEVA marks a real advance," said Professor Ingo J. Diel, M.D., Institute for Gynecological Oncology, SPGO, Mannheim, Germany. "In clinical trials XGEVA demonstrated sustained protection from SREs and also delayed the progression of pain. These factors will make a genuine difference in the lives of patients living with advanced cancer."

The marketing authorization for XGEVA is based on three pivotal, Phase 3 head-to-head trials that evaluated the effectiveness of XGEVA versus zoledronic acid at delaying SREs. The SRE clinical program for XGEVA spanned more than 50 tumor types in over 5,700 patients. In the SRE trials, XGEVA demonstrated a clinically meaningful improvement in preventing SREs compared to zoledronic acid. In these trials, XGEVA was administered every four weeks as a 120 mg subcutaneous injection, versus zoledronic acid delivered every four weeks via a 15-minute intravenous infusion, with adjustments for kidney function per the requirements of the zoledronic acid prescribing information.

In patients with breast or prostate cancer and bone metastases, XGEVA was superior to zoledronic acid in reducing the risk of SREs. In patients with bone metastases due to other solid tumors or multiple myeloma, XGEVA was non-inferior to zoledronic acid in reducing the risk of SREs. In an integrated analysis of all three studies XGEVA was superior to zoledronic acid in delaying time to first on-study SRE by 17 percent or 8.2 months (median time to first skeletal related event of 27.6 months for XGEVA and 19.4 months for zoledronic acid, ($p<0.0001$)). In this analysis, XGEVA was also superior to zoledronic acid in delaying time to first-and-subsequent on-study SRE by 18 percent ($p<0.0001$).

In patients with mild or no pain at baseline, time to worsening pain was delayed for XGEVA compared to zoledronic acid (198 versus 143 days) ($p=0.0002$). The time to pain improvement was similar for XGEVA and zoledronic acid in each study and the integrated analysis.

Overall rates of adverse events and serious adverse events were generally similar between XGEVA and zoledronic acid. Osteonecrosis of the jaw (ONJ) was seen in approximately 1-2 percent of patients, with no statistically significant difference between treatment arms. Hypocalcemia was more frequent in the XGEVA treatment group. Overall survival and progression-free survival were similar between arms in all three trials.

"Today's approval of XGEVA marks the culmination of many years of research and innovation by Amgen scientists, beginning with the discovery of the RANK Ligand pathway and the understanding of its role in bone biology to the development of the denosumab oncology clinical program," said Willard H. Dere, M.D., senior vice president and international chief medical officer at Amgen. "XGEVA promises to make a real difference for patients with cancer whose daily lives are affected by the consequences of bone metastases."

About XGEVA

XGEVA is the first and only RANK Ligand inhibitor approved in the EU for the prevention of SREs (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from solid tumors. XGEVA is the first novel bone metastases treatment for advanced cancer patients in more than a decade.

XGEVA is a fully human monoclonal antibody that binds to RANK Ligand, a protein essential for the formation, function and survival of osteoclasts (the cells that break down bone). XGEVA prevents RANK Ligand from activating its receptor, RANK, on the surface of osteoclasts, thereby decreasing bone destruction.

XGEVA is delivered as an every four week 120 mg subcutaneous injection and is not associated with renal toxicity or acute phase reactions.

XGEVA Regulatory Status

XGEVA is currently approved in the United States (U.S.) for the prevention of SREs in patients with bone metastases from solid tumors. XGEVA was approved following a six month priority review by the U.S. Food and Drug Administration (FDA). In the U.S., XGEVA is not indicated for the prevention of SREs in patients with multiple myeloma.(i) XGEVA is also approved in Canada for reducing the risk of developing SREs in patients with bone metastases from breast cancer, prostate cancer, non-small cell lung cancer, and other solid tumors. In Canada, XGEVA is not indicated for reducing the risk of developing SREs in patients with multiple myeloma.(ii)

Amgen has also submitted marketing applications for XGEVA in Australia, Mexico, Russia and Switzerland. In Japan, Amgen is working with its licensing partner, Daiichi-Sankyo Company, Limited and a marketing application was submitted in August 2010. In addition,Amgen and GlaxoSmithKline (GSK) have a collaboration agreement for the commercialization of XGEVA in a number of countries where Amgen does not currently have a commercial presence. In these countries, marketing applications are filed by GSK.

XGEVA Important Safety Information

XGEVA can cause severe hypocalcemia. Correct pre-existing hypocalcemia prior to XGEVA treatment. Monitor calcium levels in patients at greater risk of developing hypocalcemia. Administer calcium and vitamin D in all patients (unless hypercalcemia is present). Advise patients to contact a healthcare professional for symptoms of hypocalcemia.

ONJ can occur in patients receiving XGEVA. Patients who are suspected of having or who develop ONJ while on XGEVA should receive care by a dentist or an oral surgeon. In these patients, extensive dental surgery to treat ONJ may exacerbate the condition.

Adverse reactions in patients receiving XGEVA included fatigue/asthenia, hypophosphatemia, nausea, dyspnea and diarrhea.

Please visit http://www.amgen.com for full U.S. prescribing information.

Bone Metastases and SREs: Prevalence and Impact

Bone metastases occur in more than 1.5 million patients with cancer worldwide and are most commonly associated with cancers of the prostate, lung and breast, with incidence rates as high as 90 percent of patients with metastatic disease. (iii), (iv), (v), (vi)

Approximately 50-70 percent of cancer patients with bone metastases will experience debilitating SREs. (vii), (viii), (ix) Events considered to be SREs include fractures, spinal cord compression and severe bone pain that may require surgery or radiation.(x) Such events can profoundly disrupt a patient's life and can cause disability and pain. (xi), (xii), (xiii)

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit http://www.amgen.com.

Forward-Looking Statements

This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of July 15, 2011 and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, the discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further,

the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (FDA) for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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